

EMERALD MEDICAL, INC.
Mill Lane Rd.
Brimfield, MA 01010

JAN 28 1997

Premarket Notification
EMERALD MEDICAL, INC.
Nucleus Pulposis Evacuator System
Confidential

K964919

510 (k) Summary
EMERALD MEDICAL, INC.
Nucleus Pulposis Evacuator System

This summary is provided in accordance with the Safe Medical Devices Act of 1990 (SMDA). The information provided in the 510 (k), Premarket Notification, was in accordance with 21 CFR 807.87.

The EMERALD MEDICAL, INC. Nucleus Pulposis Evacuator System is an assortment of surgical instruments utilized in minimally invasive percutaneous lumbar discectomy surgical procedures.

The conclusion that the EMERALD MEDICAL, INC. Nucleus Pulposis Evacuator System is substantially equivalent to legally marketed predicate systems was reached through consideration of the requirements of substantial equivalence determinations. These requirements are set forth in the document, published on June 30, 1986 by the Center for Devices and Radiological Health (CDRH), entitled "Guidance on the Center for Devices and Radiological Health's Premarket Notification Review Program."

The new disc removal tools contain substantially equivalent technology and materials as the predicate disc removal tools utilized in the Acufex Microsurgical *Interceptre* Arthroscopic Discectomy System, 510 (k) K941709, and the Smith & Nephew *Arthroscopic MicroDiscectomy System*, AMD™. The proposed introduction kit contains the same components as the current instrument introduction systems developed by Acufex Microsurgical, Surgical Dynamics, Sofamor Danek, and Smith & Nephew Spine.

Based on the reasons provided, the EMERALD MEDICAL, INC. Nucleus Pulposis Evacuator System is substantially equivalent to legally marketed predicate minimally invasive percutaneous lumbar discectomy surgical instruments.